JAN 2 4 2011

K102670

510(k) Summary

Pursuant to 21 CFR 807.92c

Submitted By: Andrew Rodenhouse
Shoulder Innovations, LLC
4670 Fulton St E, Suite 202
Ada, MI 49301
Ph: 616-706-3903
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Date: January 18, 2011

Device Information:

Trade Name: Total Shoulder System

Common Name: Shoulder Prosthesis

Classification: 21 CFR Section 888.3650 – Shoulder joint metal/polymer non-constrained cemented prosthesis. Product Code: KWT
21 CFR Section 888.3660 – Shoulder joint metal/polymer semi-constrained cemented prosthesis. Product Code: KWS
21 CFR Section 888.3690 – Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis. Product Code: HSD

Substantially Equivalent Device:

K982981: Zimmer Bigliani/Flatow Total Shoulder System

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Device Description:

The Shoulder Innovations Total Shoulder System consists of modular humeral stems and heads, and a glenoid component. The humeral stems are manufactured from Cobalt Chrome (CoCr) and have fins to provide rotational stability. The fins have suture holes for the attachment of soft tissue and bone in the case of proximal humeral fracture. A collar is present to resist stem subsidence. The stems have a male Morse-type taper to interface with the modular humeral heads.

The humeral heads are manufactured from CoCr and are available in standard and offset configurations. The heads have a female Morse-type taper to interface with the humeral stems.

The glenoid component is manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE). The glenoid is a multi-pegged design and intended for cemented fixation only.

Intended Use:

The Shoulder Innovations Total Shoulder System is intended for use as an orthopedic implant for partial or total shoulder arthroplasty to treat the following:

- significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint;
- united humeral head fractures of long duration;
- irreducible 3- and 4-part proximal humeral fractures;
- avascular necrosis of the humeral head.

The assembled humeral component may be used alone for hemiarthroplasty or combined with the glenoid component for total shoulder arthroplasty.

The Total Shoulder System components are intended for single use only. The glenoid component is intended for cemented fixation only; the humeral stem may be implanted by press-fit or cement fixation.

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Performance Data:

Performance testing was performed on the Shoulder Innovations Total Shoulder System. The glenoid component was tested per ASTM F2028 *Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation.* The modular humeral components were tested per ASTM F2009 *Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses.* No clinical testing was performed.

Substantial Equivalence:

The results of non-clinical testing and comparative analysis demonstrate that the design, function, intended use, and indications for use of the Shoulder Innovations Total Shoulder System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 24 2011

Shoulder Innovations, LLC
% Mr. Andrew Rodenhouse
4670 Fulton Street East, Suite 202
Ada, Michigan 49301

Re: K102670
Trade/Device Name: Total Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, KWT, HSD
Dated: January 12, 2011
Received: January 12, 2011

Dear Mr. Rodenhouse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

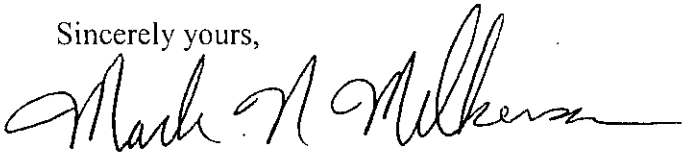
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K102670

Device Name: Total Shoulder System

Indications for Use:

The Shoulder Innovations Total Shoulder System is intended for use as an orthopedic implant for partial or total shoulder arthroplasty to treat the following:

1. significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint;
2. united humeral head fractures of long duration;
3. irreducible 3- and 4-part proximal humeral fractures;
4. avascular necrosis of the humeral head.

The assembled humeral component may be used alone for hemiarthroplasty or combined with the glenoid component for total shoulder arthroplasty.

The Total Shoulder System components are intended for single use only. The glenoid component is intended for cemented fixation only; the humeral stem may be implanted by press-fit or cement fixation.

Prescription Use X or Over-the-counter use _____
(per CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102670